REMARKS

Pursuant to and consistent with 37 C.F.R. § 1.116, entry of the foregoing amendments, and consideration of the following remarks, are respectfully requested.

At the outset, applicants would like to express their appreciation to Examiners Rao and Marschel for the courteous and helpful personal interview extended to the undersigned on January 26, 2010. During the interview various approaches were discussed for distinguishing the claimed invention from the (RS) mixture described in the applied Buchs et al document. In addition various possible new issues which might arise as the result of claim amendments were also discussed, including the issue of "obviousness." No agreement was reached.

The only rejection that remains is that of the claims under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,814,635 to Buchs et al ("Buchs"). However, Buchs does not disclose the invention as presented in the proposed claims.

As recognized by the Examiner in rejecting the claims, Buchs describes a mixture of R and S diastereoisomers, i.e., "sodium-leucovorin or potassium-leucovorin or sodium-N(5)-methyl-5,6,7,8-tetrahydrofolic acid or potassium-N(5)-methyl-5,6,7,8-tetrahydrofolic acid both of which are in the racemic form (R and S)". In this regard, the Examiner has held that the claims as currently drafted ("comprising") do not preclude racemic mixtures. The present Amendment addresses this point.

In particular, the claims as re-drafted are directed to concentrated, stable aqueous solutions of (6S)-sodium-folinate or (6S)-potassium-folinate where the solutions contain a diastereoisomeric excess of the (6S) stereoisomers. Such a solution is not disclosed or suggested by Buchs. The solutions of Buchs contain 50% of the inactive (6R) configuration.

Applicants are mindful of the legal authority suggesting that particular stereoisomers can be prima facie obvious from their racemic mixtures. See e.g., Sanofi-Synthelabo v. Apotex Inc., 2008 U.S. App. Lexis 24991 (Fed. Cir. 2008); Aventis Pharma Deutschland GmbH v. Lupin Ltd., 499 F.3d 1293 (Fed. Cir. 2007); Forest Labs Inc. v. Ivax Pharm. Inc., 501 F.3d 1263 (Fed. Cir. 2007). But that notion will not hold when the isomers would have been difficult for a person of ordinary skill in the art to separate. *Id.*

Here there is no enabling disclosure of a technique useful for obtaining the invention. Indeed, the claims call for solutions of (6S)-sodium-folinate or (6S)-potassium-folinate. As taught in the specification these solutions are prepared from *amorphous* (6S)-folinic acid (see also claim 29), which, in turn, has been prepared from (6S)-calcium-folinate (see also claim 30). As explained in the Specification, (6S)-folinic acid itself, much less (6S)-sodium-folinate or (6S)-potassium-folinate, could not be obtained following the teachings of the prior art. In particular, Example 6 of EP 0 293 029 seems to suggest that (6S)-folinic acid can be obtained by the careful addition of hydrochloric acid to an aqueous solution of calcium-(6S)-folinate. However, following those teachings the applicants were only able to obtain an untreatable, rubber like product despite the fact that various parameters were varied such as temperature, concentration and reaction time. See pages 2-3 of the Specification.

Therefore, in view of the foregoing, it is respectfully submitted that the amended claims are patentable. Accordingly, withdrawal of all rejections and the issuance of a Notice of Allowance are believed to be next in order. Such actions are earnestly solicited.

In the event that there are any questions concerning this Amendment or the application in general, the Examiner is invited to contact the undersigned so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4047.

Respectfully submitted,
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